

PRIVACY POLICY

Introduction

The Better Outcomes Registry and Network (“**BORN**”) is a provincial program for which the Children’s Hospital of Eastern Ontario – Ottawa Children’s Treatment Centre (CHEO) with respect to is a prescribed person under the *Personal Health Information Protection Act, 2004* (“**PHIPA**”) and regulation 329/04 to PHIPA (“**Regulation**”). BORN was established for the purpose of facilitating and/or improving the provision of health care in Ontario, with a vision for the best possible beginnings for lifelong health.

BORN’s program mandate is to facilitate or improve the provision of health care for patients through conception, pregnancy and delivery, and for newborns and children up to the age of 18 years (collectively “**Health Care Recipients**”) in Ontario through the collection, use and disclosure of data, together with related services. This includes:

- Provide data and analysis of data to any person who makes a written reasonable request for the data, including for the purposes of research and non-research, in accordance with BORN policies and procedures as required by the Information and Privacy Commissioner of Ontario (“**IPC**”) for a prescribed registry.
- Using best efforts to ensure that organizations that provide data to BORN, including fertility clinics, hospitals, midwifery practice groups, birthing centers, primary care providers, laboratories and other health information custodians (“**Submitters**”), do so in a timely manner;
- Maintaining and improving collection of data related to: in-vitro fertilization treatment cycles; Prenatal Screening; fetal anomalies; early pregnancy loss; genetics, including cytogenetics; pregnancy, labour and birth; perinatal loss, including stillbirth; specialized infant care, including neonatal intensive care units and special care nurseries; newborn screening and follow-up; infant mortality; and early childhood;
- Ensuring that the data is comprehensive, valid and reliable, including by developing and implementing a data quality strategy and engaging with Submitters to ensure a robust acknowledgement process;
- Providing information to Submitters, including information through dashboards and reports that identifies possible missed newborn screens to Newborn Screening Ontario;
- analysis of data to identify gaps, issues and trends in maternal and child health status and care;
- Maintaining and building relationships with Submitters through the BORN’s provincial perinatal engagement team;
- Provide performance and benchmarking reports to Ontario’s maternal-newborn-pediatric networks.
- Provide networks with standardized reports that facilitate their roles in helping health care providers plan and deliver care, promote best practices, perform quality assurance, and monitor outcomes;

- Publishing a public report bi-annually;
- Monitor and evaluate the performance of prenatal screening;
- Establish and promote systematic approaches to Prenatal Screening in Ontario;
- Provide education, information and support to health care providers, pregnant individuals and their families through knowledge mobilization efforts;
- Support of the work of the Prenatal Screening Ontario (“**PSO**”) expert committees;
- Engage with stakeholders including patients and families;
- Develop evidence-based advice for delivering Prenatal Screening and clinical care;
- Ensuring availability of non-invasive prenatal testing (i.e., screening for common aneuploidies using cell-free fetal DNA analysis) (“**NIPT**”) throughout Ontario including:
 - Developing a process for the selection of laboratories that will conduct NIPT testing in Ontario
 - Maintaining contracts through CHEO with laboratories in Ontario that are responsible for NIPT
 - Collaborating with laboratories responsible for NIPT to address issues in a timely way in the interest of patient care.
 - Implementation of standards (e.g. universal requisition)
 - Assessing and planning for local needs.

BORN collects personal health information from health information custodians for the purpose of facilitating or improving the provision of health care pursuant to s. 39(1)(c) of PHIPA. The data that is collected without patient consent from Submitters is clinically important to assisting conception, pregnancy or delivery and newborn care. The data that BORN collects, uses, discloses and manages is stored predominantly in the cloud-hosted BORN Information System (“**BIS**”) using hosting services in Ontario with disaster recovery services available in facilities located in Quebec. Smaller extracts and/or other BORN Holdings received outside the BIS are stored on BORN’s Internal PHI Storage Vault with access limited to those BORN Agents with a need for access according to their employment or contract and scope of duties.

BORN created the BIS to assist Submitters in their provision of data and to provide such Submitters and other health care providers with reports to be used to facilitate or improve the provision of health care. The BIS stores, processes, manages, analyzes, and shares information (in the form of system-generated reports) that are made available to its Submitters and other health information custodians pursuant to data sharing agreements that incorporate end user terms for those individuals who have been granted access rights by their organization (i.e., typically a health information custodian or BORN). At the request of the Ministry of Health, BORN also created the Midwifery Invoicing System (“**MIS**”) using a subset of data from the BIS and that also includes unaccommodated client information, with real-time updating, representing course of care information to ensure that health care professionals can bill and be paid for the services rendered in the provision of health care. BORN also maintains a fertility information system within the BIS that is logically separated from other data and is referred to as “**CARTR Plus**”. This includes fertility treatment data received from Submitters at fertility clinics in Ontario and other de-

identified information. Recently, BORN invested in a proof-of-concept of a BORN data warehouse (“**BDW**”). For the purposes of a pilot, BORN included a limited subset of BIS data in the BDW, focusing on a limited set of variables to evaluate the design and concept. In the future, BORN anticipates creating a broader dataset in the BDW environment based on the BIS. BORN also anticipates procuring and implementing a business intelligence solution to further support these objectives in collaboration with CHEO at a later date.

The BIS, the MIS, and the BDW (in development) are collectively referred to as the “**BORN Systems**”. The phrase “**BORN Services**” includes the BORN Systems and the services made available through the BORN Systems including reports, tools and data quality validation services that are delivered to end users. BORN also has practices and procedures that are implemented (not fully automated and not part of the “**BORN Services**”) for developing and delivering ad hoc reports and data requests that include information and analysis of data to any person who makes a reasonable written request, including for the purposes of research and non-research.

Facilitating or Improving the Provision of Health Care in Ontario – BORN’s Purposes

The BORN purpose (“**BORN Purposes**”) are ways that the BORN registry facilitates or improves the provision of health care for Health Care Recipients, as well as for informing other stakeholders and health care professionals involved in the delivery, planning and administration of health care services in Ontario. These are listed in the following:

- A. Identifying where certain health care services have not been offered or made sufficiently available to Health Care Recipients to facilitate access to such services. ⁱ
- B. Facilitating continuous improvement of health care delivery tools to minimize adverse outcomes for Health Care Recipients. ⁱⁱ
- C. Identifying where outcomes for Health Care Recipients are statistically discrepant with accepted norms. ⁱⁱⁱ
- D. Enabling health care providers to improve care to Health Care Recipients by providing them with reports to compare themselves with peers and/or benchmarks. ^{iv}
- E. Knowledge translation to improve the quality and efficiency of care for Health Care Recipients. ^v
- F. Providing health care providers with comprehensive and timely reports to support quality improvement ^{vi}, effective planning ^{vii}, administration and management of health care delivery for Health Care Recipients. ^{viii}
- G. Enabling the provision of technologies within BORN Services to improve efficiencies, data accuracy, and data protection for Providers and Health Care Recipients. ^{ix}
- H. Creating and providing reports:
 - for surveillance^x or to support local planning, coordination among providers, and implementation of provincial standards and guidelines. ^{xi}

- to make health care service delivery easier and more efficient for Submitters, health care providers, and Health Care Recipients who receive such services.^{xii}
- for public use designed to help prevent disease or injury or to promote health^{xiii};
- to educate professionals involved in the delivery of health care^{xiv}; and
- to educate potential researchers interested in improving health care.^{xv}

This list is non-exhaustive of the possible ways to use data in the BORN registry to facilitate or improve the provision of health care in Ontario. BORN uses this list of BORN Purposes in the administration of its procedures to ensure that we collect and use data within the scope of the authorities granted in PHIPA. This list is also considered by BORN when examining decisions to maintain current collections of data, and all other non-research use of data within the registry. New or revised BORN Purposes are added through a governance process at the Data Holding Committee and are informed by advice from stakeholder consultation processes, privacy specialists (internal and external), legal advisors (internal and external), and/or expertise gained through CHEO's involvement in BORN's operations and governance processes. BORN Purposes are also incorporated into data sharing agreements with health information custodians who are Submitters as a non-exhaustive list of examples of ways that BORN uses personal health information to facilitate or improve the provision of health care, and they are applied in decision making regarding collection, use, retention and the potential disclosure of data through the data governance processes implemented by BORN in addition to other controls described in this Plan.

Research

Research is not a BORN Purpose listed above; however, under the strict requirements set out in PHIPA and its Regulation, BORN is permitted to conduct research at BORN and facilitate research by external researchers who are not BORN Agents. This research can sometimes result in improvements to health care. All research is conducted under a set of rules that protect patient privacy and data is always de-identified or de-personalized to the maximum extent possible for the research project.

BORN Services are not permitted to be used for research by end users and the End User Terms and user notices are designed to require this. However, BORN does have procedures to enable research that involves the use of BORN data. These procedures are designed to ensure that research is authorized under PHIPA and its Regulation, is supported by appropriate agreements in accordance with the requirements established by the IPC and is conducted according to a research plan meeting the requirements of the Regulation under PHIPA that has been reviewed and approved by an authorized Research Ethics Board.

CHEO's Status as a Prescribed Person

BORN has a privacy and security accountability framework to implement its status and overall responsibility as a prescribed person under PHIPA and its Regulation.

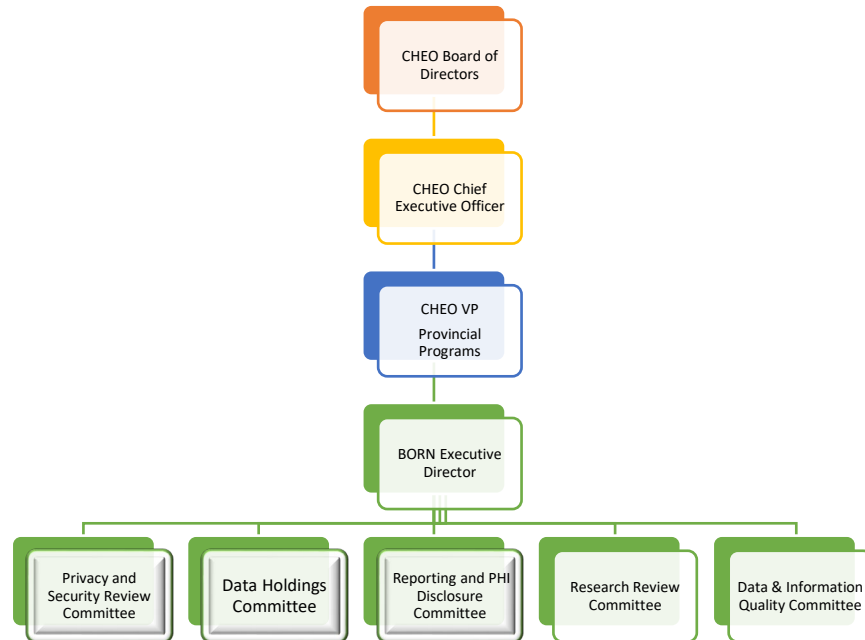


Figure 1: Accountability Structure

Status of Prescribed Registry

The Children's Hospital of Eastern Ontario (CHEO) is a prescribed person in respect of BORN as provided for in section 13(1) of the Regulation, enacted under PHIPA for the purposes of facilitating or improving the provision of health care for Health Care Recipients.

Section 13(2) of the Regulation requires BORN, as a prescribed registry, to:

- Have in place practices and procedures to protect the privacy of individuals whose personal health information BORN receives
- Maintain the confidentiality of that information
- Have its practices and procedures approved by the IPC every three years

BORN is committed to complying with the provisions of PHIPA and its Regulation applicable to a person holding a registry, as well as any other applicable legislation.

Privacy and Security Accountability Framework

BORN has developed comprehensive privacy and security policies and procedures to ensure compliance with PHIPA and its Regulation.

As illustrated in figure 1, BORN’s accountability is through CHEO. CHEO’s CEO has delegated responsibility for ensuring compliance with PHIPA and its Regulation to BORN’s Executive Director, together with ensuring compliance with the privacy and security policies, procedures and practices implemented. Also illustrated are a number of internal data committees that have been established to provide guidance, form working groups to achieve certain objectives established by the committees, and to provide advice to BORN’s Executive Director on matters of privacy, security and the collection, quality, and disclosure of data. The Executive Director also receives guidance from other teams, including the BORN Executive Team and the BORN Leadership Team.

Privacy and Security Review Committee (“PSRC”)

The PSRC has the mandate to review and approve the necessary elements of BORN’s privacy and security frameworks that are required for compliance with PHIPA and its Regulation as well as with requirements for registries issued by the IPC. Identifying and managing risk is part of the culture and day to day responsibility of all BORN staff. The PSRC is the escalation authority for significant privacy and security risks faced by BORN. In addition to the Privacy Officer and Security Officer, all BORN managers attend this committee with the Executive Director.

Data Holdings Committee (“DHC”)

The DHC ensures that the data that BORN collects is aligned with one or more BORN Purpose^{xvi} or are otherwise authorized by law in relation to use for research^{xvii}, that BORN collects only the personal health information that is reasonably necessary to meet those purposes and that a current listing and brief description of BORN’s Holdings is developed and maintained, including maintaining a mapping of the BORN Holdings to the BORN Purposes or for the purpose of facilitating research. This includes identifying new BORN Purposes that may facilitate or improve the provision of health care using data. The Data Holdings Committee receives advice through stakeholder consultation processes^{xviii}. The Data Holdings Committee may also form working groups for projects that warrant additional expertise or time.^{xix}

Reporting and PHI Disclosure Committee (“RPDC”)

The RPDC is responsible for reviewing and approving all requests for the disclosure of personal health information pursuant to PHIPA and its Regulation. The RPDC also reviews and approves record level (i.e., non-aggregated) de-identified data disclosure requests (including those requested for research and approved of by the Research Review Committee). The RPDC is also responsible for reviewing any changes and improvements to the methods used to De-identify personal health information under **P-24: De-identification and Aggregation**. The RPDC endeavors to ensure that the policy and procedures used for de-identification are based on an assessment of the actual risk of re-identification. The RPDC also reviews and approves system-generated reports in the BORN Services that are made available through the BORN Services and record-level de-identified data disclosures.

Research Review Committee (RRC)

The RRC is responsible for reviewing, approving and/or denying requests for the use and/or disclosure of personal health information for research. Additionally, in the case of (1) disclosure of personal health information for research; or (2) any disclosure of “record level” (i.e., non-aggregated) de-identified data for research a second review and approval is also required at the RPDC.

Data & Information Quality Committee (DIQC)

BORN is an authoritative source of accurate, trusted, and timely data used to monitor, evaluate, and plan for the best possible beginnings for lifelong health. The purpose of the DIQC is to facilitate the implementation and refinement of BORN's data and information quality framework, including overseeing and assessing the quality of data and developing and implementing plans, processes and tools to enhance data and reporting quality. The Data & Information Quality Committee may also make recommendations to the Data Holding Committee related to data quality in connection with collection or retention decisions.

Additional Roles and Responsibilities

The Executive Director has delegated responsibility for:

- Day to day management of privacy matters to the Privacy Officer
- Day to day management of information security matters to the Information Security Officer
- Management of Ad hoc reporting and research to Manager of Health Outcomes
- Management of Indigenous Data Governance Policy to the Indigenous Wellness Coordinator.
- Management of system generated reporting to the Manager of Health Networks

The duties and responsibilities of the Privacy Officer focus on developing and maintaining a strong culture of privacy at BORN and include:

- Management of the privacy program, including monitoring compliance, conducting regular audits and providing reports to senior management and recommendations for changes to policies or procedures
- Execution of privacy training
- Execution and oversight of privacy impact assessments
- Responding to inquiries or complaints related to BORN privacy practices
- Any and all related privacy oversight

The duties and responsibilities of the Information Security Officer include managing the security program as follows:

- Monitoring compliance, conducting regular audits and providing reports to senior management and recommendations for changes to policy or procedures
- Execution of security training
- Execution and oversight of threat and risk assessments
- Execution and oversight of vulnerability assessments
- Any and all related security oversight
- Responsibility for the technology used to collect and securely store the Personal Health Information used by BORN

The Data Request and Research Coordinators have been delegated responsibility implementing the Ad hoc reporting processes (both non-research and research). These Coordinators also work very closely with the Privacy Officer to help ensure that they comply with the requirements of this Plan.

Collection of Personal Health Information

BORN collects personal health information for the purpose of facilitating or improving the provision of health care (i.e., see the BORN Purposes described in the Introduction section above) or as otherwise permitted under PHIPA and its Regulation. BORN Holdings consist of the following:

BORN Information System (BIS)

The BORN Information System is a single data holding comprised of personal health information collected from health information custodians and other organizations as listed in the data holding statement of purpose.

The unique data collections within the BIS are provided by these various health information custodians and other organizations for specific maternal, newborn, and child encounters with the health care system, including:

- Prenatal screening laboratory results (including ultrasound information)
- Prenatal and pediatric cytogenetics results
- Genetics/MFM Encounter (formed by the merger of Prenatal screening follow-up and Antenatal specialty for fetal anomalies information)
- Antenatal general for pregnancy status and care information
- Labour information, birth and postpartum information for mothers and babies
- Special care nursery and Neonatal intensive care unit information
- Newborn screening laboratory and results information
- Newborn screening follow-up for diagnosis information
- Ontario Antenatal Record from Family Health Teams (primary care pilot project)
- Fertility information from the CARTR Plus (Canadian Assisted Reproductive Technology Plus) database
- Well baby and child data for standardized assessment tools (Rourke Baby Record Ontario, Nipissing District Developmental Screen) as well as height and weight
- Autism information from the Child and Adolescent Needs and Strengths tool
- Healthy Baby Healthy Child (HBHC) provincial screening tool
- CANImmunize- Historical datasets from a pilot with participating public health units
- Niday Perinatal and NICU/ICU Database (after 2010)

Other Holdings:

- Ontario Midwifery Invoicing System (MIS)
- COVID-19 infection and vaccination data
- Infant death registration files^{xx}
- Canadian Institute for Health Information (CIHI) Discharge Abstract Database (DAD) and National Ambulatory Care Reporting System (NACRS) records data
- Maternal and child health card numbers for Niday records, plus prenatal OHIP billing codes

Closed Holdings:

- FAN (Fetal Alert Network) historical database
- Ontario prenatal screening historical database
- Niday Perinatal and NICU/ICU historical database
- Ontario Midwifery historical database
- CARTR (Canadian Assisted Reproductive Technology) historical database
- NIPT (non-invasive prenatal testing) historical database
- Cytogenetics historical database

The types of personal health information collected include demographic information (e.g. date of birth, postal code) and clinical information about conception, fetuses, newborn babies, children and their pregnant parent (including pregnancy history, medical history and a summary of care provided during pregnancy, labour, birth and the newborn and early childhood periods).

BORN does not collect personal health information if other information will serve the purpose and does not collect more personal health information than is reasonably necessary to meet the BORN Purposes outlined above. The conceptual model used is based on the following:

Identifiers + Health Status + Health Risk Factors + Care Provided = Health Outcomes

High-quality information in each of these categories helps BORN fulfill the BORN Purposes defined above. Clinical data in BORN Holdings provide the authoritative information and context required to make the decisions and conclusions in support of the registry function. To illustrate, we use the example of a caesarean birth at 36 weeks, which would be appropriate for a pregnant person with preeclampsia, but not for a healthy first-time pregnant person with no risk factors and good health status. When studying caesarean section rates, it is important to differentiate between these two scenarios before drawing conclusions about the care being provided.

BORN collects only those data elements that have been identified through the review process undertaken by the Data Holdings Committee. Data Holdings Committee has been delegated responsibility for:

- Reviewing new proposed BORN Holdings
- Maintaining Statements of Purpose of Data Holdings s for each BORN Holding
- Maintaining BORN Purposes to ensure that they remain current and within the scope of facilitating or improving the provision of health care;

BORN is committed to not collecting (i) Person Health Information if other information will serve the purpose; and (ii) more personal health information than is reasonably necessary to meet BORN's Purposes.

For further information in relation to the purposes, elements and sources of each data holding of personal health information please contact dataholding@bornontario.ca or see the BORN Website^{xxi}.

Use of Personal Health Information

BORN uses the personal health information that it collects for the purposes of facilitating or improving the provision of health care as generally described in the Introduction under the heading “*Facilitating or Improving the Provision of health care in Ontario – BORN’s Purposes*”. BORN also uses personal health information for research.

BORN ensures that each identified use of personal health information is consistent with the uses of personal health information permitted by PHIPA and its Regulation. BORN does not use personal health information if other information will reasonably serve the purpose and does not use more personal health information than is reasonably necessary to meet the purpose, using de-identified or aggregate or de-personalized information wherever possible.

Use for Ad Hoc Reporting

BORN uses reasonable efforts to provide de-identified ad hoc reports to any Data Requestor who makes a reasonable written request within the BORN Purposes or research. Ad hoc reports to data requestors pursuant to a Data Request for non-research use do not contain personal health information^{xxii}. The reports are carefully reviewed to ensure there is no foreseeable risk of re-identification through small cell counts or other forms of possible residual disclosure in accordance with BORN’s policy and procedure regarding **De-identification and Aggregation**.

Additionally, all data requestors are required to agree to written terms that require that end users not use the information in these reports to attempt to re-identify the data included in any de-identified report (alone or in combination with other information) to identify an individual, including any attempt to decrypt information that is encrypted or identifying an individual based on unencrypted information and/or prior knowledge (except to the extent expressly permitted by law).

The procedures involved when data requestors request data for research purposes have additional requirements including review at BORN’s Research Review Committee, confirmation that the research plan includes all requirements set out in the Regulation, and confirmation that the research plan has been approved by an authorized Research Ethics Board. There are additional requirements including the execution of a research agreement that meets the requirements of PHIPA and additional requirements of the IPC.

Use for System Generated Reports

System generated reports are also provided electronically within the BORN Services. These system-generated reports have been designed by BORN to facilitate or improve health care. These reports are typically aggregated rather than expressed at a record level. In respect of system-generated reports, Reporting Analysts ensure that system generated reports have been aggregated according to BORN’s policy and procedure regarding **De-Identification and Aggregation** except to the extent approved of by the RPDC. For example, in some case, end users are entitled to search “into” the report to find errors

within the data (such end users being agents of the Submitters who supplied such data) or for the purposes of providing direct patient care (such end users being within the circle of care, such as in the case of following up on unsatisfactory screens), or for training purposes to improve health care delivery at the Submitter. Submitters may also have access to their data as provided to the registry for archival and audit purposes.

In addition to data aggregation, user notices and contracts are also used to protect this information in the BORN Services. For example, system-generated reports are also provided electronically within the BORN Services to end users of organizations who have a data sharing agreement with BORN. The BORN Services are made available to end users under End User Terms that restrict use of the BORN Services for the purpose of facilitating or improving the provision of health care at an end user's organization or, if applicable, for assisting in providing health care to the individual to whom the personal health information relates and only to the extent and for tasks that are within the course of the end user's approved duties and not contrary to the limits imposed on the end user by their organization. Use of the BORN Services for research is prohibited under those same terms.

Additionally, all end users who receive any reports through the BORN Services are required under the terms to not use the information in these reports to attempt to re-identify the data included in any report (alone or in combination with other information) to identify an individual, including any attempt to decrypt information that is encrypted or identifying an individual based on unencrypted information and/or prior knowledge (except to the extent expressly permitted by law).

Technology is also used to protect this information. Privilege access controls are also used in the BORN Services to protect the information in this system-generated reports. For example, access privileges for end users in the BORN Services are established according to the roles at the Submitter on a "need to know" basis and assigned accordingly by the System Administrator. Also, Submitters may audit all accesses by end users through the electronic logs created (as provided for in the data sharing agreements between Submitters and CHEO).

Use by BORN for Research

BORN uses personal health information to create reports for stakeholders for BORN Purposes as described above. Additionally, BORN may also use personal health information for research only when the strict requirements of PHIPA are adhered to, including review at BORN's Research Review Committee, confirmation that the research plan includes all regulatory requirements, and confirmation that the research plan has been approved by an authorized Research Ethics Board. In such context, personal health information is stored and used on BORN's Internal PHI Storage Vault for research purposes.

BORN remains responsible for personal health information used by its Agents and access and use by BORN Agents is strictly controlled. Also, agents are trained on their privacy obligations and sign a Confidentiality Agreement on an annual basis acknowledging the requirements to use only the information necessary for their work as permitted by these policies, to keep personal health information

secure at all times, and to notify BORN of any discovered or suspected breach as BORN's policies and procedures regarding:

- **Limiting Agent Access to and Use of Personal Health Information**
- **Privacy Breach Management**
- **Privacy and Security Training and Awareness**
- **Execution of Confidentiality Agreements by Agents**

BORN Agents who have access to data containing personal health information that have additional requirements related to third party agreements that have use restrictions or conditions that vary from normal processes. BORN has implemented practices and procedures to ensure compliance with these additional requirements. For example, access to one data set requires that the BORN Agents be listed in the agreement, and they are also required to swear or affirm Oaths of Secrecy before a public notary related to the access and use of such data. These processes are further described in BORN's policy and procedure regarding **Limiting Agent Access to and Use of Personal Health Information**.

Disclosure of Personal Health Information

BORN permits disclosure of personal health information for research as authorized under PHIPA and its Regulation. Researchers must meet the requirements for research disclosure provided in section 44 of PHIPA and associated Regulation. BORN will not disclose personal health information for research purposes if other information will serve the research purpose. Also, BORN will not disclose more personal health information than is reasonably necessary to meet the identified research purpose.

BORN also permits the disclosure of personal health information for purposes other than research only in the following circumstances in accordance with the PHIPA and the Regulation:

1. For the purpose for which the health information custodian was authorized to disclose the information under section 49(1)(a) of PHIPA
2. For the purpose of carrying out a statutory or legal duty as per section 49(1) (b) of PHIPA
3. To a prescribed planning entity under section 13(5) of the Regulation

BORN does not disclose personal health information if other information serves the purpose and does not disclose more personal health information than is reasonably necessary to meet the purpose unless the use or disclosure is required by law^{xxiii}.

Personal health information is disclosed to the following groups:

- to end users of BORN Services who are agents at a health information custodian for the purpose of facilitating or improving the provision of health care at that organization (including data quality purposes, training related to improving the provision of health care, or for audit and archival at the Submitter) or, if applicable, for use in providing health care to the individual to

whom the personal health information relates and only to the extent and for tasks that are within the course of the agent's approved duties and not contrary to the limits imposed on that agent by their organization (e.g., missed newborn screens and the HBHC program delivered by Public Health Units)^{xxiv};

- To researchers for research (as described above);
- To an entity under section 13(5) of the Regulation under PHIPA for use according to policies and procedures that meet similar requirements established at that entity.

BORN has specific policies and procedures that apply to these activities:

- **Disclosure of Personal Health Information for Purposes other than Research**
- **Disclosure of Personal Health Information for Research Purposes and the Execution of Research Agreements**
- **De-Identification and Aggregation**

Disclosure of De-identified and/or Aggregate Personal Health Information

BORN uses personal health information to create reports for data requestors and certain end users of BORN Services for BORN Purposes. All such reports are aggregated or otherwise de-identified.

For ad hoc reports, the Data Request and Research Coordinator and the Data Analysts trained to use the de-identification software tools have responsibility for following procedures to de-identify or aggregate ad hoc reports prior to disclosure to ensure that it is not reasonably foreseeable in the circumstances that the information could be used, either alone or with other information, to identify an individual. These BORN Agents are supported by the Reporting and PHI Disclosure Committee (the committee who also oversees system-generated reports) in respect of any questions they may have regarding risk of re-identification. BORN has also retained expert consultants to further help develop expertise in this area and may provide limited access to personal health information by such experts for such purposes subject to compliance with this Plan.

Secure Retention, Transfer and Disposal of Records containing Personal Health Information

BORN prohibits paper records of personal health information.

BORN ensures that electronic records are kept safe and secure as follows:

- Electronic records of personal health information are securely retained in identifiable format within the transactional database for 28 years after which they are converted to a de-identified format and then securely destroyed. Secure retention, timeline, and secure destruction are detailed in BORN's policy and procedures regarding:

- **Secure Retention of Records of Personal Health Information**
- **Secure Disposal of Records of Personal Health Information**
- Electronic records of personal health information are securely transferred and disposed of in accordance with BORN's policies and procedures regarding:
 - **Secure Transfer of Records of Personal Health Information, and**
 - **Secure Disposal of Records of Personal Health Information**

Implementation of Administrative, Technical and Physical Safeguards

BORN has in place administrative, technical and physical safeguards to protect the privacy of individuals whose personal health information is received and to maintain the confidentiality of that information. BORN takes steps to protect personal health information against theft, loss and unauthorized use or disclosure and to protect records of personal health information against unauthorized copying, modification, or disposal. These safeguards are set out in BORN's policies and procedures regarding:

- **Information Security Policy**
- **Passwords**
- **Back-up and Recovery of Records of Personal Health Information**
- **Acceptable Use of Technology**
- **Execution of Confidentiality Agreement by Agents**

Privacy and security policies and procedures are reviewed at least once prior to each scheduled review by the IPC pursuant to subsection 13(2) of the Regulation under PHIPA by the Privacy and Security Review Committee in accordance with BORN's policies and procedures regarding Ongoing Review of Security Policies and Procedures. BORN has implemented these policies, procedures, and practices to protect the privacy of individuals whose personal health information it receives and to maintain the confidentiality of that information.

Inquiries, Concerns or Complaints Related to Information Practices

All inquiries, concerns or complaints related to the privacy policies and procedures of BORN and BORN's compliance with PHIPA and its Regulation must be directed to:

Privacy Officer
BORN Ontario
Centre for Practice Changing Research building
401 Smyth Road
Ottawa ON K1H 8L1
Email: privacy@BORNOntario.ca

See the BORN website at www.BORNOntario.ca

Individuals may also direct complaints regarding the compliance of BORN to the Information and Privacy Commissioner of Ontario:

Information and Privacy Commissioner of Ontario
2 Bloor Street East
Suite 1400
Toronto, ON M4W 1A8

Telephone:
Toronto Area: 416-326-3333
Toll Free (within Ontario): 1-800-387-0073
TDD/TTY: 416-325-7539
Fax: 416-325-9195

Transparency of Practices in Respect of Personal Health Information

In addition to this Privacy Policy, BORN Ontario provides Frequently Asked Questions, a list of data holdings of personal health information and other information at the BORN website at www.bornontario.ca to meet its transparency policy. If more information is helpful, readers are asked to contact the Privacy Officer as per above.

Compliance Audit and Enforcement

BORN Agents must comply with the policies and procedures and practices set out in the Privacy and Security Management Plan. Compliance is audited on an ongoing basis by the Privacy Officer and the Information Security Officer in accordance with BORN's policies and procedures regarding **Privacy Audits** and **Security Audits**. Consequences of breach are detailed in each respective breach policy as well as in BORN's Privacy Policy. BORN's policies and procedure regarding **Discipline and Corrective Action** clarifies:

The BORN Ontario Confidentiality Agreement states that a breach of the terms of the Confidentiality Agreement, BORN Ontario policies and procedures, and/or the provisions of the Personal Health Information Protection Act, 2004 may result in disciplinary action which can include termination of employment or legal action

Notification of Breach

BORN Agents are required to notify the Privacy Officer or the Information Security Officer at the first reasonable opportunity of a breach or suspected breach in accordance with BORN's policies and procedures regarding **Privacy Breach Management** or **Security Breach Management**, as applicable.

¹ For example, Newborn Screening Ontario (NSO) is a provincial program operated at CHEO that tests for rare diseases in newborns. Test results can lead to early identification and potentially life-saving treatment. By

collecting data on births in the province and then cross-referencing to test results from NSO, system-generated reports delivered through the BORN Information System can promptly identify babies that have not been tested and facilitate access to such testing.

ⁱⁱ For example, BORN endeavors to improve screening algorithms by leveraging data in the BORN Information System (BIS) to minimize missed screens, as well as false-positive and false-negative test results. This is important because the anxiety for pregnant individuals and families waiting for test results as well as the impact(s) of receiving a false negative or a positive screen can be significant, and at times, catastrophic. By gathering all screening results and all associated follow-up and outcome information in the BIS, trained analysts can review the information to identify potentially inaccurate results. Once analyzed, the thresholds in the screening algorithms can be adjusted to improve screening quality and reduce false-positive and false-negative results.

ⁱⁱⁱ As an authoritative source of maternal-child health outcomes information, BORN provides data to enable timely knowledge about related health trends in the population. For example, BORN data have been used to examine potential clustering of congenital anomalies by geographic region. or whether there is variation in the number of episiotomies compared to existing benchmarks or in comparison to other parts of the province, which could potentially lead to poorer outcomes.

^{iv} With data on births across the province, BORN is well-positioned to facilitate access to key comparators by geographic region and/or level of care for health care providers. BORN Dashboards and benchmark indicators are therefore delivered in aggregated system-generated reports to Health Information Custodians that provide data to BORN. These reports are used to inform care and to help identify potential opportunities for improvement of care outcomes.

^v BORN uses data to help identify strategies for continuous quality improvement before conception, throughout pregnancy, at delivery, and following delivery. For example:

- BORN Data are used to inform the improvement of assisted reproductive technologies for people who wish to have children and would benefit from these health care services. For example, BORN delivers an annual report for the International Committee Monitoring Assisted Reproductive Technologies (ICMART) to help fertility clinics incorporate evidence-based information into their practices.
- Prenatal Screening Ontario (PSO) is operated through BORN and provides services in respect of the identification of common aneuploidies in Ontario through the development of a quality assurance framework for prenatal screening. This includes promotion of a universal approach to prenatal screening in Ontario through standards and practice guidelines development, provision of support to health care providers and the public through knowledge mobilization efforts, supported by the PSO Expert Committees, and engagement of stakeholders including patients and families. BORN Data is also used to improve the reliability of ultrasounds offered to pregnant persons. For example, by minimizing errors in Nuchal translucency (NT) measurement accuracy of prenatal screening results can improve, reducing false positives and false negatives and the often-associated repeat tests and analyses.

^{vi} Health care providers routinely collect key clinical information as part of every visit such as, the indications for interventions, the timing of labour, the medications and analgesia administered and outcome for the pregnant person and baby. It is when these data are aggregated that important trends in the care being provided can be highlighted.

^{vii} For example, Public Health Units use BORN data presented in system-generated reports to plan the delivery of services in their regions. These reports can also provide feedback to Public Health Units and health promotion agencies on the effects of their campaigns related to targets such as smoking cessation, breastfeeding promotion, and prenatal class attendance. Understanding the relations between these campaigns and newborn and childhood outcomes can help improve the care provided to pregnant persons and children.

^{viii} For example, BORN collects clinical and administrative data elements associated with the billing agreement between the Ministry of Health and the Ontario midwifery community. Such information is used to create system-

generated reports within the Midwifery Invoicing System (MIS) at BORN to inform the provincial billing for midwife services rendered.

^{ix} For example, BORN may pre-populate certain data elements within the BORN Information System (BIS) for use by or between Health Information Custodians who are within the circle of care of a pregnancy and/or resulting delivery (including post-partum care and newborn care). This reduces the amount of data that some health care providers need to manually enter (since the data would otherwise be entered by care provider).

^x For example, BORN provides de-identified record-level information to the Public Health Agency of Canada (PHAC) for the Canadian Congenital Anomalies Surveillance System (CCASS). The annual process includes a rigorous de-identification process, including grouping for sensitive variables (e.g. maternal age groups instead of age or date of birth; month and year of birth rather than full date of birth), and review through de-identification software tools.

^{xi} For example, BORN data are used to develop reports for regional networks in Ontario related to prenatal, newborn and child health in order to support local planning, coordination among providers, and implementation of provincial standards and guidelines to improve quality of care across the province.

^{xii} For example, the Healthy Babies Healthy Children (HBHC) program is a free and voluntary way that expectant parents can learn about having a healthy pregnancy and birth, and how to help a child grow and develop through the use of public health unit-delivered services that are available to new parents. For those expectant or new parents who opt to participate in the HBHC program, BORN facilitates service provision by providing data collected from health information custodians to public health units under data sharing agreements. This data is delivered by BORN through the Ministry of Children, Community and Social Services who is serving as a health information network provider to facilitate the secure transfer of data between BORN and public health units. The data that is received by public health units are used for the purpose of delivering the program services to parents who have opted to receive such program.

^{xiii} For example, BORN publishes a public report bi-annually, including information that (i) illustrates the utility of the Data in supporting indicators that are relevant to reproductive and child health; (ii) highlights maternal-child health issues, trends and outcomes found by analyzing the Data; and (iii) provides information to Submitters and the broader public sector for their decision making and policy development regarding maternal-child health and reproductive outcomes.

^{xiv} Certain reports that are prepared for the Ministry of Health or other stakeholders are also publicly available at BORN's websites for the purpose of educating the public on matters of public health or to inform the public to prevent disease or injury or to promote health or educate professionals involved in the delivery of health care. These reports are reviewed by the BORN management team prior to publication to ensure that there is public interest in making the reports publicly available to prevent disease or injury or to promote health and to ensure the information is not published in a form that could reasonably enable a person to ascertain the identity of an individual. For example, BORN data are used to inform pregnant persons about the impact(s) of COVID infections and vaccination during pregnancy.

^{xv} BORN may assist potential researchers with interest in using BORN data for research to improve health care. For example, when a potential researcher is developing a proposal for future research, BORN may be asked to provide aggregate data to inform the development of the research plan pursuant to BORN's data request process, essentially educating the researcher as to what is possible. Typically, the purpose of the potential research being planned, were it to be conducted, would improve health care.

^{xvi} See the Introduction above where the current BORN Purposes are listed and described.

^{xvii} For example, the infant death registration files received from the Ministry of government and Consumer Services (MGCS) is received under the *Vital Statistics Act* for undertaking statistical, epidemiological or other research that is in the public interest.

^{xviii} These include feedback from one or more of BORN's clinical advisory committees, for example, the Maternal Newborn Outcomes Committee (MNOC), the Midwifery Advisory Committee (MAC), the Neonatal Working Group, the Cytogenetics Working Group, and Prenatal Screening Ontario stakeholder groups such as Genetics and NT Working Groups.

^{xix} For example, in 2021 the Data Holdings Committee established an external health equity advisory committee comprised of over twenty stakeholders to provide additional expertise in an advisory capacity regarding the collection and use of Data to improve health care and access for vulnerable groups. The Data Holdings Committee also established the Enhancement Working Group comprised of specialists within BORN to recommend and implement enhancements to the BORN Systems used to receive Data from Submitters and create system-generated reports.

^{xx} Only for statistical, epidemiological or other research that is in the public interest.

^{xxi} For example, see : <https://www.bornontario.ca/en/data/data-holdings.aspx>, https://www.bornontario.ca/Modules/DataDictionary/Encounters_and_AlphabeticalLists.aspx and the BORN Data Dictionary.

^{xxii} Future exceptions may however arise as BORN has a policy and procedures in place that allows for disclosure of personal health information for the purposes of facilitating or improving the provision of health care under Section 49(1)(a) of PHIPA in limited circumstances. For example, in the future, where a First Nation requests personal health information for the purposes of facilitating or improving the provision of health care to patients who belong to such First Nation, BORN may disclose personal health information to Indigenous Peoples if all of the requirements of PHIPA and its Regulation are met. In respect of such disclosures, the exercise of this authority would be subject to case-by-case approval in collaboration with the IPC to ensure appropriate protections of patient privacy are in place.

^{xxiii} Subsection 49(2) of PHIPA provides that subject to the exceptions and additional requirements, if any, that are prescribed, a person who is not a health information custodian, and to whom a health information custodian discloses personal health information, shall not use or disclose more of the information than is reasonably necessary to meet the purpose of the use or disclosure, as the case may be, unless the use or disclosure is required by law.

^{xxiv} As noted above, future examples of disclosures under s. 49(1)(a) of PHIPA may arise outside of system-generated reports as BORN has a policy and procedures in place that allows for the disclosure of personal health information for the purposes of facilitating or improving the provision of health care under Section 49(1)(a) of PHIPA in limited circumstances.